

**UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION**

UNITED STATES OF AMERICA <i>ex rel.</i> [FILED UNDER SEAL], Plaintiffs-Relators, v. [FILED UNDER SEAL], Defendants.	FILED UNDER SEAL DO NOT PLACE ON PACER CIVIL ACTION NO.:2:19-cv-02596-DCN JURY TRIAL DEMANDED
--	--

RELATOR'S COMPLAINT UNDER THE FALSE CLAIMS ACT

**UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION**

UNITED STATES OF AMERICA <i>ex rel.</i> JANE DOE, <p style="text-align: center;">Plaintiff-Relator,</p> <p style="text-align: center;">v.</p> GENOA HEALTHCARE, LLC and GENOA HEATLHCARE HOLDINGS, LLC, <p style="text-align: center;">Defendants.</p>	FILED UNDER SEAL DO NOT PLACE ON PACER CIVIL ACTION NO.: 2:19-cv-02596-DCN JURY TRIAL DEMANDED
--	---

RELATOR’S COMPLAINT UNDER THE FALSE CLAIMS ACT

Plaintiff-Relator Jane Doe (“Relator”), on behalf of the United States of America, brings this action against Defendants Genoa Healthcare LLC and Genoa Healthcare Holdings, LLC (collectively “Genoa Healthcare”) for violations of the False Claims Act (“FCA”), 31 U.S.C. § 3729, *et seq.*, to recover all damages, civil penalties, and all other recoveries provided for under the FCA.

I. SUMMARY OF THE CASE

1. The South Carolina Department of Mental Health (“DMH”) provides critical mental health services through a statewide network of inpatient and outpatient facilities. Practitioners at DMH often prescribe one or more medications to DMH patients. These medications, especially when provided in injectable form, tend to be extremely expensive and thus provide a lucrative opportunity for pharmacies that provide the medications to DMH and DMH patients.

2. Genoa Healthcare promotes itself as the country’s largest provider of pharmaceutical services for individuals suffering from mental health issues. As relevant here,

Genoa Healthcare previously provided on-site pharmaceutical and related services at DMH locations across South Carolina. Beyond actually filling prescriptions, during different periods of time, these services included time-consuming administrative and bureaucratic services, such as helping patients apply for financial assistance for prescription medication and assisting patients with completing the necessary paperwork to obtain prior authorizations for prescription medications

3. Relator is a licensed psychiatrist who works at DMH. During her employment, she learned the incredible fact that Genoa Healthcare was providing these services for free. DMH was not paying Genoa Healthcare, notwithstanding that DMH would otherwise have to perform these services on its own and that the services imposed a significant burden upon Genoa Healthcare. This fact was confirmed to Relator by various sources, including insiders at Genoa Healthcare.

4. Genoa Healthcare did not provide the services for free as a magnanimous gesture. Rather, it exploited its relationship with DMH to effectuate a classic kickback scheme in which it provided a kickback (performance of the services for free) in return for (1) direct and unparalleled access to DMH patients and (2) increased business from DMH and its patients. For example, when assisting a DMH patient obtain financial assistance, Genoa Healthcare directly interacted with the patient and fostered goodwill with the patient. As Genoa Healthcare knew, this in turn, would drastically increase the likelihood that the patient would choose to receive prescriptions from Genoa Healthcare.

5. Genoa Healthcare operates across the country. For the reasons described below, in addition to its misconduct with respect to DMH's statewide network of facilities in South Carolina, Relator has good reason to believe that Genoa Healthcare is effectuating the same kickback scheme in other locations.

6. Based on Relator's firsthand experience, the overwhelming majority of DMH patients are beneficiaries of federal healthcare programs, including Medicare and Medicaid. Reimbursement claims made to government healthcare programs (such as Medicare and Medicaid) that are tainted by kickbacks are false claims within the meaning of the False Claims Act. Accordingly, by engaging in the above-described misconduct, Genoa Healthcare presented false claims to government healthcare programs and is thus liable for this conduct under the False Claims Act.

II. THE PARTIES

A. The Government

7. The United States is a plaintiff to this action on behalf of the Department of Health and Human Services ("HHS"), the Centers for Medicare and Medicaid Services ("CMS"), and federally funded healthcare programs, including Medicare and Medicaid.

B. Relator

8. Relator is a medical doctor and licensed psychiatrist. She attended the Medical University of South Carolina in Charleston, South Carolina and obtained her M.D. degree in 2006. Following medical school, her general psychiatry residency at Medical College of Georgia was from 2006-2009 and her Child and Adolescent Psychiatry Fellowship there was from 2009-2011. Relator is a member of the American Psychiatric Association and is board certified in psychiatry.

9. Relator works at the South Carolina Department of Mental Health, and as described below, has directly observed Genoa Healthcare's misconduct underlying her claims.

10. Relator has standing to bring this action pursuant to 31 U.S.C. §3730(b)(1).

11. Relator's complaint is not based on public disclosures of the allegations or transactions discussed herein within the meaning of 31 U.S.C. § 3730(e)(4)(A).

12. Relator is an original source of the information provided herein within the meaning of 31 U.S.C. § 3730(e)(4)(B).

13. Prior to filing this action, Relator voluntarily disclosed to the United States the information on which the allegations or transactions discussed herein are based within the meaning of 31 U.S.C. § 3730(e)(4)(B).

C. Defendants

14. Defendant Genoa Healthcare, LLC is a limited liability corporation, which upon information and belief, is incorporated in Oregon.¹

15. Defendant Genoa Healthcare Holdings, LLC is, upon information and belief, the parent company of Genoa Healthcare LLC and, upon information and belief, is incorporated in Delaware.

16. This Complaint collectively refers to Defendant Genoa Healthcare, LLC and Defendant Genoa Healthcare Holdings, LLC as “Genoa Healthcare.”

III. JURISDICTION AND VENUE

17. Jurisdiction is founded under 31 U.S.C. § 3732(a) and (b), 28 U.S.C. §§ 1331, 1345, and 1367(a).

18. Personal jurisdiction and venue are proper in the District of South Carolina pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a), because Genoa Healthcare transacts and has transacted business in the District of South Carolina.

¹ All allegations in this complaint made “upon information and belief” are allegations that are “likely [to] have evidentiary support after a reasonable opportunity for further investigation or discovery” within the meaning of Rule 11(b)(3).

IV. LEGAL AND REGULATORY BACKGROUND

A. The False Claims Act

19. The FCA “was passed in 1863 as a result of investigations of the fraudulent use of government funds during the Civil War.” United States v. Neifert-White Co., 390 U.S. 228, 232 (1968).

20. The FCA “establishes a scheme that permits either the Attorney General or a private party to initiate a civil action alleging fraud on the Government,” U.S. ex rel. Eisenstein v. City of New York, New York, 556 U.S. 928, 932 (2009) (citations omitted), and “imposes significant penalties on those who defraud the Government.” Universal Health Servs., Inc. v. United States, 136 S. Ct. 1989, 1995 (2016).

21. The FCA provides, *inter alia*, that any person who (1) “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” or (2) “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,” is liable to the United States for a civil monetary penalty plus treble damages. 31 U.S.C. § 3729(a)(1)(A)-(B).

22. The terms “knowing” and “knowingly” mean “that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b)(1)(A)(i)-(iii).

23. Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

24. The term “claim” means “any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (1) is presented to an officer, employee, or agent of the United States; or (2) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the

Government’s behalf or to advance a Government program or interest, and if the United States Government (a) provides or has provided any portion of the money or property requested or demanded; or (b) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded” 31 U.S.C. § 3729(b)(2)(A)(i)-(ii).

25. “[T]he term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4).

26. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 and 64 Fed. Reg. 47099, 47103 (1999), the civil monetary penalties under the FCA are \$5,500 to \$11,000 for violations occurring on or after September 29, 1999 but before November 2, 2015. See 28 C.F.R. § 85.3.

27. Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and 83 Fed. Reg. 706 (Jan. 8, 2018), the civil monetary penalties under the FCA were adjusted to \$11,181 to \$22,363 for violations occurring on or after November 2, 2015 that are assessed after January 29, 2018. See 28 C.F.R. § 85.5.

B. The Anti-Kickback Statute

28. The federal Anti-Kickback Statute (“AKS”) makes it a criminal offense to “knowingly and willfully” offer, pay, solicit, or receive any remuneration to induce, or in return for, referrals of items or services paid for by a Federal health care program. 42 U.S.C. § 1320a-7b. If any purpose of the remuneration is to induce or reward the referral or recommendation of business payable in whole or in part by a federal health care program, the AKS is violated, *i.e.*, a lawful purpose will not legitimize a remuneration that also has an unlawful purpose.

29. Specifically, the AKS provides:

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(1)-(2).

30. “Federal health care program” is defined as “(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of Title 5); or (2) any State health care program, as defined in section 1320a-7(h) of this title.” 42 U.S.C. § 1320a-7b(b)(1).

31. “Federal health care program” includes both Medicare and Medicaid.

32. While “[i]n some industries, it is acceptable to reward those who refer business to you. However, in the Federal health care programs, paying for referrals is a crime.”²

² HHS-OIG, A Roadmap for New Physicians Fraud & Abuse Laws, available at <https://oig.hhs.gov/compliance/physician-education/01laws.asp>.

33. Violation of the AKS can subject the perpetrator to exclusion from participation in federal healthcare programs and civil monetary penalties of \$50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7); 42 U.S.C. § 1320a-7a(a)(7).

34. In addition, reimbursement claims to federal health care program that are tainted by violations of the AKS are false claims within the meaning of the FCA. 42 U.S.C. § 1320a-7b(g) (“In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31.”).

C. Medicare and Medicaid

35. Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq., established the Medicare program.

36. Medicare is a health insurance program funded by the federal government that provides health insurance benefits to (1) individuals who are 65 or older, (2) individuals with certain disabilities, and (3) individuals suffering from end stage renal disease. See 42 U.S.C. §1395c.

37. Medicare is administered by CMS, which in turn, is a constituent agency of HHS.

38. Medicare is comprised of four parts: Part A, Part B, Part C, and Part D.

39. Medicare Part A authorizes payment for institutional care, including hospital, skilled nursing facility and home health care.

40. Medicare Part B authorizes payment for physician and ancillary services, including laboratory and diagnostic tests and procedures. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and contributions from the federal treasury. CMS contracts with private insurance companies to administer, process and pay Part B claims. The private

insurance companies that contract with CMS to provide these services are called Medicare Administrative Contractors, previously known as Part B carriers.

41. Medicare Part C is also known as Medicare Advantage. Medicare Advantage Plans stand in place of Medicare Parts A and B and are offered by private companies approved by Medicare called Medicare Advantage Organizations. Medicare Advantage Plans may also offer prescription drug benefits ordinarily available under Medicare Part D. These plans are typically less expensive for the consumer, but limit covered beneficiaries to a network of covered providers.

42. Medicare Part D, which is particularly relevant to the allegations raised herein, provides optional prescription drug coverage for Medicare beneficiaries.

43. Medicaid was created on July 30, 1965, through Title XIX of the Social Security Act.

44. Medicaid is a cooperative federal-state program through which the federal government provides financial assistance to states so that they may furnish medical care to needy individuals. 42 U.S.C.S. § 1396 et seq.

45. The federal portion of States' Medicaid payments, the Federal Medical Assistance Percentage, is based on a State's per capita income compared to the national average. The federal portion consisted of a minimum of 50% up to a maximum of roughly 80%.

46. As relevant to the allegations in this Complaint, both Medicare and Medicaid generally cover reasonably necessary mental health services subject to various coverage requirements and limitations.³

³ See generally CMS, Medicare & Your Mental Health Benefits, available at <https://www.medicare.gov/pubs/pdf/10184-medicare-mental-health-bene.pdf>; CMS, Behavioral Health Services, available at <https://www.medicare.gov/medicaid/benefits/bhs/index.html>.

V. FACTUAL BACKGROUND

A. **Genoa Healthcare's Operations**

47. Individuals suffering from behavioral health and psychiatric issues are often prescribed one or more medications. See generally NATIONAL INSTITUTE OF MENTAL HEALTH, Mental Health Medication, available at <https://www.nimh.nih.gov/health/topics/mental-health-medications/index.shtml> (“Medications can play a role in treating several mental disorders and conditions.”).

48. Genoa Healthcare claims that it is “the largest provider of pharmacy and outpatient telepsychiatry services dedicated to individuals with behavioral health and complex, chronic conditions.”⁴

49. As relevant here, Genoa Healthcare offers on-site pharmaceutical services to medical providers who provide behavioral health and psychiatric services.

50. Genoa Healthcare will establish an on-site pharmacy at the medical provider's office to be staffed by one or more pharmacists and support staff. This enables patients to fill their prescriptions on-site without having to go to a separate pharmacy, and as a result, it increases the likelihood that a patient will actually have their prescription filled.

51. The establishment and maintenance of an on-site pharmacy is only economically viable for Genoa Healthcare if a substantial number of prescriptions are written and filled at that location.

52. For smaller practices where it would not be economically viable to maintain an on-site pharmacy, Genoa Healthcare offers “remote dispensing sites” at providers' offices that are

⁴ See Genoa Health, About us, available at <https://www.genoahealthcare.com/about-us/>.

staffed by a pharmacy technician with remote oversight by a pharmacist through audiovisual means.

53. For even smaller practices where it would not be economically viable to maintain a remote dispensing site, Genoa Healthcare offers a “Consumer Medication Coordinator,” although in some regions, this title has been transitioned to “Account Services Representative.”

54. As further described below, a Consumer Medication Coordinator coordinates and delivers patients’ prescriptions by working with a local Genoa Healthcare pharmacy, in addition to providing other services.

55. Upon information and belief, a Consumer Medication Coordinator is not a trained pharmacist or pharmacy technician.

56. Genoa Healthcare says that it “serves more than 800,000 individuals annually across the United States.”

57. As of March 2018, Genoa Healthcare operated in 45 states and the District of Columbia, and upon information and belief, presently operates in 47 states and the District of Columbia.

58. In or around September 2018, Genoa Healthcare was purchased by UnitedHealth Group Inc. for approximately \$2.5 billion.

B. Relator’s Work at the South Carolina Department of Mental Health

59. Relator presently works at the South Carolina Department of Mental Health (“DMH”). Relator previously worked at DMH from 2012-2015 and returned to DMH in 2016.

60. In South Carolina, DMH “support[s] the recovery of people with mental illnesses . . . by providing comprehensive programs that range from inpatient care to school-based services.”⁵

⁵SOUTH CAROLINA SENATE MEDICAL AFFAIRS OVERSIGHT SUBCOMMITTEE, Summary Report on the South Carolina Department of Mental Health, at 2 (Mar. 2016), available at

61. DMH's statewide system "[c]omprises 17 community-based, outpatient mental health centers, each with clinics and satellite offices, which serve all 46 counties – a total of approximately 60 outpatient sites."⁶ In addition, DMH operates hospitals, nursing homes, and other facilities. *Id.* at 3.

62. DMH "[p]rovides services to approximately 100,000 patients per years, approximately 30,000 of whom are children." *Id.* at 3.

63. One of the services provided by DMH is the prescription of medications as part of the treatment and management of mental illnesses.

64. Based on Relator's work at DMH, the overwhelming majority of DMH patients are Medicare or Medicaid beneficiaries. Relator estimates that 35% of DMH patients are Medicare beneficiaries and that 65% of DMH patients are Medicaid beneficiaries (with some overlap given individuals who are eligible for both Medicare and Medicaid coverage).

VI. GENOA HEALTHCARE'S FALSE AND FRAUDULENT CONDUCT

65. Genoa Healthcare provides pharmaceutical and related services to DMH in connection with DMH's prescription of medications to its patients.

66. During her employment with DMH, Relator has observed firsthand that Genoa Healthcare implemented a multifaceted kickback scheme under which it provided an array of *free* services (described below) to DMH that DMH would otherwise have to provide at its own expense. In addition, Genoa Healthcare has implemented this scheme across the country.

<https://www.scstatehouse.gov/CommitteeInfo/SenateMedicalAffairsCommittee/OversightReports/DMH%20Final%20Report%20and%20Summary%2032316.pdf>

⁶SOUTH CAROLINA HOUSE WAYS AND MEANS HEALTHCARE SUBCOMMITTEE, *The South Carolina Department of Mental Health FY 2018-19 Budget Hearing*, at 3 (Jan 23, 2018), available at <https://www.scstatehouse.gov/CommitteeInfo/Ways&MeansHealthcareBudgetSubcommittee/January242018/2018-2019%20DMH%20Budget%20Request%20Information.pdf>

67. The free services provided by Genoa Healthcare to providers, including DMH, are a kickback in violation of the AKS. Claims to Government healthcare programs, including Medicare and Medicaid, that are tainted by these kickbacks are false claims for which Genoa Healthcare is liable under the FCA.

A. Patient Assistance Program and Prior Authorization Services

68. The free services that Genoa Healthcare provided to DMH included services related to Patient Assistance Programs (“PAP”) and prior authorizations.

69. Patient Assistance Programs (“PAP”) are programs that provide free or discounted drugs and “are offered to help defray the costs of drugs for patients of limited means.”⁷

70. Typically, PAPs “are offered directly or indirectly by a pharmaceutical manufacturer.” *Id.*

71. While PAPs can serve a legitimate and charitable purpose, “[m]any PAPs also present a risk of fraud, waste, and abuse with respect to Medicare and other Federal health care programs.” HHS-OIG, Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 FR 31120-01 (May 30, 2014).

72. For example, PAPs can be used to pay kickbacks to patients rather than to subsidize drugs for individuals with legitimate financial constraints. *See id.* at 31121 (“[I]f a PAP’s grant of financial assistance to a patient is made to influence the patient to purchase (or to induce the patient’s physician to prescribe) certain items, the [AKS] . . . could be violated.”).

⁷ Danielle Trostorff, ABA Patient Assistance Programs: History and Pharmaceutical Settlements (Mar. 19, 2019), available at https://www.americanbar.org/groups/health_law/publications/aba_health_resource/2018-2019/march/history/; *see also* *McDaniel v. Colvin*, 2014 WL 2442543, at *6 (S.D. Ill. May 30, 2014) (“Patient assistance programs are run by pharmaceutical companies to provide free medications to people who cannot afford to buy their medicine.”) (internal quotation marks omitted).

73. Thus, a manufacturer must evaluate a patient's financial need before providing any free or discounted medications through its PAP. See id. at 31122 ("PAP must determine [a patient's] eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner." Id. at 31122.

74. This evaluation is done through an application process. A patient who wants to participate in a manufacturer's PAP submits an application which, for the reasons described above, must substantiate the patient's financial hardship. A patient must periodically reapply to establish a continuing financial hardship.

75. Based on Relator's firsthand experience at DMH, the application and reapplication process for PAPs typically involves a substantial amount of work for the prescriber, such as assisting the patient by providing the required information and completing the required paperwork.

76. Until August 2016, one of the free services Genoa Healthcare provided to DMH was completing all of the paperwork necessary for a patient's application or reapplication for a PAP.

77. This was done through a Genoa on-site representative, who was typically a Consumer Medication Coordinator.

78. The Genoa representative would remain at the DMH location for an entire day, during which the representative would complete the time-consuming administrative functions with respect to a patient's application or reapplication for a PAP.

79. More specifically, the representative would meet with the patient, assist the patient with respect to completing the required paperwork, and then submit the paperwork to the appropriate company.

80. This allowed DMH to avoid performing these time-consuming functions, for which DMH (if had performed these functions) would not have received any compensation.

81. When a Genoa Healthcare representative visited a DMH location, he or she would sign in and out on a sign-in sheet. The representatives almost always were at the DMH location for the entire working day.

82. In addition to providing PAP-related services, Genoa Healthcare's Consumer Medication Coordinators also provided other services to DMH clinics.

83. These services included the facilitation of prior authorizations ("PA") of prescription medications.

84. Generally speaking, a PA is "a requirement that your physician obtain approval from your health insurance plan to prescribe a specific medication for you." Ron Gasbarro, CONSUMER AFFAIRS, My pharmacist says he needs "prior authorization" -- what's that all about? (Apr. 6, 2015), available at <https://www.consumeraffairs.com/news/my-pharmacist-says-he-needs-prior-authorization-whats-that-all-about-040615.html>; see generally Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 647 (2003).

85. Medicare and Medicaid both require prior authorizations for certain medications. See generally CMS, Prior authorization, available at <https://www.medicare.gov/node/39141>.

86. On its website, Genoa Healthcare advertises that it offers "prior authorization assistance" and describes: "We don't just fill prescriptions. We use special packaging personalized for each consumer, make proactive outreach calls, deliver medications and take care of prior authorizations."

87. Based on Relator's firsthand experience at DMH, the PA process imposes a substantial administrative burden on DMH.

88. The American Medical Association describes that “[t]he PA process is disruptive and burdensome for physicians and patients” and as a result “[p]hysicians consistently express strong concerns regarding health plans’ PA programs, as they frequently witness the negative impact of PA-caused care delays on patients. In addition, both practices and their patients suffer from the time and cost burdens imposed by PA requirements.” AMERICAN MEDICAL ASSOCIATION, Prior authorization: The current landscape, at 1-2, available at https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/premium/psa/prior-authorization-toolkit_0.pdf.

89. Furthermore, the PA process requires providers to perform uncompensated administrative and bureaucratic work. Id. at 1.

90. Until August 2016, one of the free services Genoa Healthcare provided to DMH was completing the work necessary for obtaining a PA where necessary, including for Medicare and Medicaid patients.

91. This was done through an on-site representative, who was typically a Consumer Medication Coordinator.

92. This allowed DMH to avoid performing these time-consuming functions, for which DMH (if had performed these functions) would not have received any compensation.

93. Genoa Healthcare provided onsite PAP-related and PA-related services at all DMH clinic locations with the exception of the clinics in McCormick and Greenville.

94. Genoa Healthcare stopped providing PAP-related and PA-related services at DMH locations in or around August 2016.

95. Upon information and belief, this change occurred after a local pharmacy (Long’s Pharmacy) threatened to sue Genoa Healthcare for this conduct.

96. More specifically, Relator was told that Long's Pharmacy complained to DMH and to Genoa Healthcare that Genoa Healthcare's presence onsite at DMH clinics constituted unfair competition.

97. From that point forward, Genoa Healthcare no longer provided PAP-related and PA-related services to DMH clinics, and DMH employees provided the services.

98. At certain locations, including the Edgefield location, DMH retained a former Genoa Healthcare employee named Kayle Conyers to perform the services that were previously performed by Genoa Healthcare employees.

99. Ms. Conyers left Genoa Healthcare to work for DMH in or around May 2017.

B. Injection Book Services (Beckman Center Only)

100. Some of the most common medications provided to DMH patients are provided by injections, *i.e.*, by shots.

101. DMH orders injectable medication from pharmaceutical providers, including Genoa Healthcare.

102. As described further below, this is a particularly lucrative component of Genoa Healthcare's relationship with DMH given that the injectable medications are extremely expensive and that patients typically receive a shot on a monthly basis.

103. The Beckman Center for Mental Health Services is a group of six DMH clinics serving seven counties in South Carolina.

104. The main clinic location of the Beckman Center is in Greenwood with smaller clinic locations in Edgefield, Laurens, McCormick, Newberry, and Abbeville.

105. At nearly all of the Beckman Center's clinic locations, Genoa Healthcare provided services related to DMH's provision of injectable medications to its patients. The only exceptions are the locations in Greenville and McCormick.

106. More specifically, a Genoa Healthcare representative would review patient records and the Beckman Center's inventory of injectable medications to determine which shots needed to be ordered. The Genoa representative would then prepare the paperwork necessary to order the shots from Genoa.

107. Based on Relator's experience at DMH, the performance of these functions imposed a substantial administrative burden upon the Genoa representative.

108. If Genoa Healthcare had not performed these functions, the Beckman Center would have been required to perform them.

109. Unlike the PAP-related and PA-related services – which as described above, Genoa Healthcare stopped performing for DMH in or around August 2016 – Genoa Healthcare continued to perform the injection book services at the Beckman Clinic until in or around August 2018.

110. In or around August 2018, the Beckman Center took over performance of the injection book services due to dissatisfaction with Genoa Healthcare's performance of that service.

C. DMH Did Not Pay Genoa Healthcare for These Services

111. Genoa Healthcare did not charge DMH for the provision of the above-described services, including the PAP-related services, the PA-related services, and the injection book services (collectively, the "Services").

112. Multiple Genoa Healthcare employees have confirmed to Relator that DMH did not pay Genoa Healthcare for the Services.

113. Kayle Conyers (who as described above previously worked at Genoa Healthcare and now works at DMH) personally told Relator that DMH did not pay Genoa Healthcare for the PAP-related services.

114. This discussion occurred in or around March 2019 during a telephonic conversation between Relator and Ms. Conyers.

115. One of the Genoa Healthcare representatives who performed the Services at DMH's Edgefield location was Lakeya Cunningham.

116. Ms. Cunningham also personally told Relator that DMH did not pay Genoa Healthcare for the PAP-related services.

117. This discussion occurred in early 2018 during an in-person conversation between Relator and Ms. Cunningham at the Edgefield clinic.

118. In addition, in a March 2019 email, a Genoa Healthcare employee named Alicia Polson confirmed to Relator in an email that "there wasn't any charge for the service."

119. Ms. Polson works as a business development representative out of Genoa Healthcare's office in Columbia, South Carolina.

120. In addition, in a March 2019 phone call, a Genoa Healthcare employee named Kristin Hauser confirmed to Relator that DMH had not paid Genoa Healthcare for the Services.

121. Ms. Hauser works as an Account Services Representative out of Genoa Healthcare's office in Columbia, South Carolina.⁸

122. In addition to these communications with Genoa Healthcare employees, Relator also confirmed that DMH did not pay Genoa Healthcare for the Services with Dr. Eman Sharawy.

123. Dr. Sharawy serves as the medical director of the Beckman Center for Mental Health Services, which as described above, is a group of DMH clinics serving seven counties in South Carolina with its main clinic location in Greenwood, South Carolina.

124. In or around April 2019, Relator spoke with Dr. Sharawy about the Services that Genoa Healthcare had previously provided to DMH.

⁸ Upon information and belief, all Consumer Medication Coordinators in South Carolina were transitioned to Account Services Representatives in or around August 2016 and perform similar functions.

125. Relator asked Dr. Sharawy whether DMH had paid Genoa Healthcare for the Services. Dr. Sharawy responded: “No, they did it for free. It was a situation where we gave them something and they gave us something. We gave them our office space and they did our PAP and PAs.”

126. In sum, various individuals at Genoa Healthcare and DMH have confirmed to Relator that DMH did not pay Genoa Healthcare for the Services.

D. Genoa Healthcare Provided the Free Services in Exchange for Business and for Direct Access to DMH’s Patients

127. Genoa Healthcare provided the Services for free for the express purpose of securing direct access to DMH and DMH patients, which in turn would generate business for Genoa Healthcare.

128. In this way, Genoa Healthcare’s provision of the Services to DMH was a classic kickback in establishing a *quid quo pro* relationship between DMH and Genoa Healthcare.

129. A full understanding of the nature and purpose of this relationship requires an understanding of the two different ways in which Genoa Healthcare provides medications to DMH and DMH patients: (1) DMH patients order non-injectable medications directly from Genoa Healthcare and (2) DMH orders injectable medications from Genoa Healthcare that DMH then provided to its patients.

130. With respect to non-injectable medications, DMH patients could theoretically utilize pharmacies other than Genoa Healthcare to fill their prescriptions.

131. However, Genoa Healthcare provided the Services for free for the express purpose of securing direct access to DMH patients, with the knowledge that doing so would allow it to directly solicit business from DMH patients.

132. As described above, Genoa Healthcare provided the Services through the presence of an on-site representative.

133. In addition, DMH allowed Genoa Healthcare to display promotional materials, such as posters, in its clinics.

134. While the physical presence of Genoa Healthcare representatives and promotional materials, in themselves, allowed Genoa Healthcare to generate business from DMH patients, the most significant advantage that Genoa Healthcare enjoyed was its ability to cultivate personal relationships with DMH patients.

135. For example, as described above, when Genoa Healthcare provided PAP-related services, its representative would meet with a DMH patient to complete the necessary paperwork. This provided Genoa Healthcare with direct access to DMH patients.

136. Moreover, these relationships were particularly significant given that Genoa Healthcare was assisting DMH patients with respect to obtaining prescription medications or financial assistance for prescription medications.

137. Thus, DMH patients would perceive that Genoa Healthcare was helping them obtain medical and financial benefits, thereby drastically increasing the likelihood that DMH patients would elect to receive their prescriptions through Genoa Healthcare.

138. Genoa Healthcare seized on this access to solicit business from DMH patients.

139. For example, a job posting for a consumer medication coordinator position describes that a “key function” of the position was “promoting Genoa services to obtain new consumers and increasing the number of consumers Genoa serves.”

140. The same posting describes that the “major duties and responsibilities” of the position included “[b]uild[ing] strong relationships with various Genoa partners including:

consumers, case managers, and clinic staff to educate and deliver on the services Genoa provides” and to “[e]nroll consumers in our services.” *Id.* at 3.

141. In these ways, Genoa Healthcare leverages its unique and unparalleled access to DMH patients (which it obtained by paying a kickback to DMH in the form of the free Services) to generate business.

142. Genoa Healthcare’s scheme operated slightly differently with respect to injectable medications, but with the same result.

143. Unlike non-injectable medications that are ordered by patients, injections are ordered by a DMH clinic and sent directly to the clinic.

144. While DMH clinics could conceivably use other vendors from which to order injectable medications, based on Relator’s experience at DMH, nearly all DMH clinics ordered injectable medications from Genoa Healthcare on an exclusive basis.

145. Indeed, Relator was told that only two DMH clinics did not order injectable medications from Genoa Healthcare. Tellingly, a Genoa Healthcare representative was not on-site at these locations, illustrating that the other locations’ decision to order injectable medications from Genoa Healthcare was tied to Genoa Healthcare’s provision of the Services for free.

146. A patient has no role in selecting the pharmaceutical provider from whom DMH orders injectable medications, *i.e.*, DMH unilaterally chooses to purchase the injectable medications from Genoa Healthcare.

147. DMH’s ordering of shots was particularly attractive to Genoa Healthcare, because these shots are extremely expensive.

148. For example, based on her experience at DMH, Relator estimates that 30% of the injectable medications given to DMH patients were for a medication called Abilify Maintena,

which is given on a monthly basis. The wholesale price for this injectable medication ranges from \$1,700-\$2,300 depending on the precise dosage.⁹

149. As a further example, based on her experience at DMH, Relator estimates that 30% of the injectable medications given to DMH patients were for a medication called Invega Sustenna, which is given on a monthly basis. The wholesale price for this injectable medication ranges from \$600-\$2,800 depending on the precise dosage.

150. Thus, by providing the Services to DMH for free, Genoa Healthcare was able to solicit DMH's orders of these lucrative injectable medications.

151. Highlighting the *qui quo pro* relationship between Genoa Healthcare and DMH and as described above, Dr. Sharawy (the medical director at DMH's clinic in Greenwood, South Carolina) told Relator: "No, they did it for free. It was a situation where we gave them something and they gave us something. We gave them our office space and they did our PAP and PAs."

152. In sum, Genoa Healthcare paid a kickback (the provision of the Services for free) in returned received a benefit (access to DMH's patients and increased business from DMH and its patients).

E. Nationwide Scope of Genoa Healthcare's Kickback Schemes

153. As described above, as of March 2018, Genoa Healthcare operated in 45 states and the District of Columbia.

154. Upon information and belief, Genoa Healthcare presently operates in 47 states and the District of Columbia with particularly significant operations in Colorado, Connecticut, Florida,

⁹ The "wholesale acquisition price" generally refers to the price at which a manufacturer sells its products to a wholesaler. Pharmacies mark up these prices, so the actual cost would be substantially higher.

Georgia, Illinois, Indiana, Michigan, Missouri, New Hampshire, North Carolina, Ohio, Pennsylvania, Tennessee, Texas, Virginia, and Washington.

155. Upon information and belief, Genoa Healthcare's operates its above-described kickback scheme across the country, *i.e.*, Genoa Healthcare provides free services to providers in exchange for business and direct access to patients.

156. For example, in a March 2019 email exchange, Relator asked Kayle Conyers whether Genoa Healthcare still provided the Services in other states even though it had stopped doing so in South Carolina.

157. Ms. Conyers responded: "It only affected SC. NC MHC services are privately run. It's different there than here. CMCs [consumer medication coordinators] are still stationed with those sites and in others. Like GA has a few CMCS as well. I don't know if they tracked the shots as most clinics even in SC never allowed access to CMS like I had with Beckman."

158. As a further example, the above-described job posting for a Consumer Medication Coordinator position was for a position in Lake City, Florida.

159. Genoa Healthcare released a similar job posting for an account services representative position in Glenwood Springs, Colorado, which detailed similar functions as the consumer medication coordinator job posting.

F. Representative Examples of Medicare and Medicaid Patients

160. Relator provides the following examples of Medicare and Medicaid patients for whom DMH ordered expensive injectable medications from Genoa Healthcare.¹⁰

161. Patient 1 is a Medicaid beneficiary. On or about April 26, 2019, DMH ordered 2 units of the following injectable medication for Patient 1 from Genoa Healthcare: Risperdal consta

¹⁰ Relator refers to these patients anonymously to safeguard their privacy.

50mg. The approximate wholesale cost of Risperdal consta 50mg is \$969.56/unit before accounting for any markup by Genoa Healthcare. Upon information and belief, Genoa Healthcare sought reimbursement from Medicaid for Patient 1.

162. Patient 2 is a Medicaid beneficiary. On or about April 26, 2019, DMH ordered 1 unit of the following injectable medication for Patient 2 from Genoa Healthcare: Risperdal consta 37.5mg. The approximate wholesale cost of Risperdal consta 37.5mg is \$727.16/unit before accounting for any markup by Genoa Healthcare. Upon information and belief, Genoa Healthcare sought reimbursement from Medicaid for Patient 2.

163. Patient 3 is a dual Medicare and Medicaid beneficiary. On or about April 26, 2019, DMH ordered .8 units of the following injectable medication for Patient 3 from Genoa Healthcare: Invega Sustenna 117mg. The approximate wholesale cost of Invega Sustenna 117mg is \$1337.13/unit before accounting for any markup by Genoa Healthcare. Upon information and belief, Genoa Healthcare sought reimbursement from Medicare and Medicaid for Patient 3.

164. Patient 4 is a Medicaid beneficiary. On or about April 26, 2019, DMH ordered .8 units of the following injectable medication for Patient 4 from Genoa Healthcare: Invega Sustenna 117mg. The approximate wholesale cost of Invega Sustenna 117mg is \$1337.13/unit before accounting for any markup by Genoa Healthcare. Upon information and belief, Genoa Healthcare sought reimbursement from Medicaid for Patient 4.

165. Patient 5 is a Medicaid beneficiary. On or about April 26, 2019, DMH ordered 1.5 units of the following injectable medication for Patient 5 from Genoa Healthcare: Invega Sustenna 234mg. The approximate wholesale cost of Invega Sustenna 234mg is \$2674.31/unit before accounting for any markup by Genoa Healthcare. Upon information and belief, Genoa Healthcare sought reimbursement from Medicaid for Patient 5.

166. Patient 6 is a dual Medicare and Medicaid beneficiary. In or about April 2019, DMH ordered 1 units of the following injectable medication for Patient 6 from Genoa Healthcare: Invega Sustenna 156mg. The approximate wholesale cost of Invega Sustenna 156mg is \$1782.92/unit before accounting for any markup by Genoa Healthcare. Upon information and belief, Genoa Healthcare sought reimbursement from Medicare Medicaid for Patient 6.

167. Patient 7 is a dual Medicare and Medicaid beneficiary. In or about April 2019, DMH ordered 1 units of the following injectable medication for Patient 7 from Genoa Healthcare: Invega Sustenna 234mg. The approximate wholesale cost of Invega Sustenna 235mg is \$2674.31/unit before accounting for any markup by Genoa Healthcare. Upon information and belief, Genoa Healthcare sought reimbursement from Medicare and Medicaid for Patient 7.

G. Genoa Healthcare's Presentment of False Reimbursement Claims

168. Based on Relator's firsthand experience at DMH, Genoa Healthcare directly bills a patient's insurance carrier (Medicare, Medicaid, or otherwise) and bills the patient for any co-pay.

169. This includes both (1) injectable medications first provided by Genoa Healthcare to DMH and subsequently provided by DMH to its patients and (2) non-injectable medications directly provided by Genoa Healthcare to DMH patients.

170. Thus, upon information and belief, Genoa Healthcare submitted reimbursement claims to government healthcare programs (including Medicare and Medicaid) for medications provided to DMH patients.

171. For example, upon information and belief, Genoa Healthcare submitted reimbursement claims to Medicare and Medicaid for Patients 1-7 above.

172. Genoa Healthcare is a private for-profit company.

173. As described above, Genoa Healthcare receives reimbursement from insurance carriers for medications provided to DMH patients. Thus, with respect to beneficiaries of

government healthcare programs, Genoa Healthcare would *not* get paid if it did *not* seek and receive reimbursement from the government.

174. As a for-profit company, there would be no reason for Genoa Healthcare to provide free services to DMH if Genoa Healthcare did not subsequently seek reimbursement for the medications provided to DMH patients.

175. This is particularly evident given that Genoa Healthcare's entire relationship with DMH was a kickback scheme, which exposed Genoa Healthcare to substantial financial and other penalties under the FCA and AKS. It would make little sense for Genoa Healthcare to risk exposure to such penalties if it were not seeking reimbursement for the medications provided to DMH patients, *i.e.*, there would be no reason for Genoa Healthcare to implement a fraudulent scheme if there were no financial reward resulting from the scheme.

176. In addition, as described above, the overwhelming majority of DMH patients to whom Genoa Healthcare provides medications are Medicare and/or Medicaid beneficiaries.

177. In sum, with respect to DMH patients who are beneficiaries of government healthcare programs (including Patients 1-7), it is evident that Genoa Healthcare submitted reimbursements claims to the government for the medications provided to those patients. See United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180 (5th Cir. 2009) ("It would stretch the imagination to infer...that the defendant doctors go through the charade of meeting with newly hired doctors to describe their fraudulent practice and that they continually record unprovided services only for the scheme to deviate from the regular billing track at the last moment so that the recorded, but unprovided, services never got billed.").

VII. GENOA HEALTHCARE'S FALSE CLAIMS LIABILITY

178. As described above, the AKS broadly prohibits the payment of "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in

kind to any person to induce such person . . . to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.” 42 U.S.C. § 1320a-7b(b)(2).

179. The free services that Genoa Healthcare provides to providers, including DMH, violate the AKS. See Health Choice Grp., LLC v. Bayer Corp., 2018 WL 3637381, at *22 (E.D. Tex. June 29, 2018) (finding that a relator adequately alleged an FCA claim where “the allegations raise a question as to whether the free nurse and reimbursement support services provided by Defendants eliminated an expense Prescribers would otherwise have had to incur”); United States v. Medtronic, Inc., 189 F. Supp. 3d 259, 270 (D. Mass. 2016) (“[E]ven a physician *legitimately* billing Medicare for properly-supervised . . . clinic services has received remuneration when he otherwise would have had to expend additional money or time to administer the services himself or pay staff to do so.”).

180. These AKS violations serve as the predicate for Genoa Healthcare’s liability under the FCA.

181. The FCA prohibits “knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval” and “knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim.” 31 U.S.C. § 3729(a)(1)(A).

182. “Any claim tainted by an AKS violation constitutes a false or fraudulent claim” for purposes of the FCA. United States v. Berkeley Heartlab, Inc., 225 F. Supp. 3d 487, 499 (D.S.C. 2016); see 42 U.S.C. § 1320a-7b(g) (“[A] claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of” the FCA.”).

183. As described above, upon information and belief, Genoa Healthcare submitted reimbursement claims tainted by AKS violations to government healthcare programs, including Medicare and Medicaid, for medications provided to DMH patients. This specifically includes reimbursements claims to Medicare and/or Medicaid for medications provided to Patients 1-7.

VIII. COUNTS

COUNT I

Violation of the False Claims Act - 31 U.S.C. §3729(a)(1)(A)

184. Relator repeats and re-alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

206. In violation of 31 U.S.C. §3729(a)(1)(A), Genoa Healthcare knowingly presented false or fraudulent claims for payment or approval to (1) officials of the United States and/or (2) contractors, grantees, or other recipients of money provided by or that would be reimbursed by the United States.

207. The false statements made by Genoa Healthcare had a natural tendency to influence or be capable of influencing the payment of the claims, and in fact, did influence the payment of the claims.

208. Genoa Healthcare made fraudulent and false statements with actual knowledge of the falsity of its statements, with deliberate ignorance of the falsity of its statements, or with reckless disregard as to the falsity of its statements.

209. By virtue of the false or fraudulent claims that Genoa Healthcare presented, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT II
False Claims Act – Violation of 31 U.S.C. §3729(a)(1)(B)

210. Relator repeats and re-alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

211. In violation of 31 U.S.C. §3729(a)(1)(B), Genoa Healthcare knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims to (1) the United States or (2) contractors, grantees, or other recipients of money provided by or that would be reimbursed by the United States.

212. The false records and statements made by Genoa Healthcare had a natural tendency to influence or be capable of influencing the payment of the claims, and in fact, did influence the payment of the claims.

213. By virtue of the false records and statements made by Genoa Healthcare, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

REQUEST FOR RELIEF

WHEREFORE, Relator, on behalf of the United States, demands that judgment be entered in their favor and against Genoa Healthcare for:

- (1) Three times the amount of damages to the United States;
- (2) Civil penalties of (1) no more than \$11,000 and no less than \$5,500 for each violation of the FCA that occurred after September 29, 1999 but before November 2, 2015 and
(2) no more than \$22,363 and no less than \$11,181 for each violation of the FCA that occurred on or after November 2, 2015;
- (3) Any other recoveries or relief provided for under the FCA;

- (4) Relator's receipt of the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs, based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action; and
- (5) Such other relief as the Court may deem appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), a jury trial is demanded in this case.

Dated: September 13, 2019

Respectfully submitted,

**RICHARDSON, PATRICK,
WESTBROOK & BRICKMAN, LLC**

/s/ Terry E. Richardson, Jr.
Terry E. Richardson, Jr., ID No.: 3457
P.O. Box 1368
Barnwell, SC 29812
Tel: (803) 541-7850
E-mail: trichardson@rpwb.com

T. Christopher Tuck, ID No.: 9135
1037 Chuck Dawley Blvd.
Building A
Mt. Pleasant, SC 29464
Tel: (843) 727-6500
E-mail: ctuck@rpwb.com

Sherrie R. Savett (*pro hac vice* forthcoming)
E-mail: ssavett@bm.net
Russell D. Paul (*pro hac vice* forthcoming)
E-mail: rpaul@bm.net
Jonathan Z. DeSantis (*pro hac vice* forthcoming)
Email : jdesantis@bm.net

BERGER MONTAGUE

1818 Market Street, Ste. 3600

Philadelphia, PA 19103

Tel: (215) 875-3000

Fax: (215) 875-4604